UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen – ASD-ADHD Products Liability Litigation **This Document Relates To: All Cases**	**22md3043 (DLC)**

FIRST AMENDED MASTER LONG FORM COMPLAINT AND JURY DEMAND AGAINST JOHNSON & JOHNSON CONSUMER INC.

Plaintiffs, by and through their Counsel and pursuant to the Court's Orders, Dkt. 609, 647, and 724, bring this First Amended Master Long Form Complaint and Jury Demand ("Master Complaint") against Defendant Johnson & Johnson Consumer Inc. ("JJCI").

For decades, Johnson & Johnson ("J&J") and its subsidiaries have manufactured, marketed and sold Tylenol® ("Tylenol").[1] The active ingredient in Tylenol is acetaminophen (sometimes referred to as APAP), which is claimed by JJCI to be one of the only safe pain relievers for pregnant women. That market is highly lucrative for JJCI, as approximately 65% of pregnant women—having been lulled into a false sense of security by JJCI's claims that Tylenol is safe—take acetaminophen over the course of their pregnancy. But for at least ten years, scientific evidence has shown that ingesting Tylenol during pregnancy poses grave risks that JJCI has never disclosed. That evidence shows that Tylenol dramatically increases the risk that a fetus will develop neurodevelopmental disorders, like autism spectrum disorder ("ASD") and attention-deficit/hyperactivity disorder ("ADHD").

[1] Tylenol, as used in this Complaint, includes only Tylenol products with acetaminophen as the sole active ingredient, such as TYLENOL® Regular Strength and TYLENOL® Extra Strength. These two products are intended to serve as examples and are not to be considered an exhaustive list of Tylenol products that may be identified in Plaintiffs' Short Form Complaints.

JJCI's failure to warn women of Tylenol's risks has caused life-altering consequences for families across the country. Pregnant women have relied on and continue to rely on JJCI's representations regarding Tylenol's safety, and their reliance has resulted in their children developing ASD and/or ADHD, disabilities for which there are no cures. The law entitles pregnant mothers to choose, after thoughtfully weighing the risks and benefits of taking Tylenol, whether the benefits of consuming the drug is worth the increased risk that their unborn children will develop ASD and/or ADHD. Had they been properly apprised of those risks, the mothers in these cases would have elected to entirely avoid or substantially reduce their Tylenol consumption while pregnant. Had they made those informed decisions, their children would not have developed ASD or ADHD.

Each Plaintiff is a child, parent, or guardian who has suffered injuries due to a mother's prenatal use of Tylenol that caused her child to develop ASD or ADHD. This First Amended Master Complaint sets forth allegations of fact and law common to Plaintiffs' claims against JJCI, but "the [M]aster [C]omplaint is not meant to be a pleading with legal effect but only an administrative summary of the claims brought by all the plaintiffs." *Gelboim v. Bank of Am. Corp.*, 574 U.S. 405, 413 (2015). Consistent with this principle, the First Amended Master Complaint is not an operative pleading, does not necessarily include all claims asserted in all the actions in this multidistrict litigation ("MDL"), and is not intended to merge for any purpose the separate actions in this MDL. Any individual facts, jurisdictional allegations, additional legal claims, and/or requests for relief of an individual Plaintiff may be set forth as necessary in a Short Form Complaint or filing by the respective Plaintiff. A Short Form Complaint is the operative pleading for any individual action, and it may incorporate by reference any or all of this First Amended Master Complaint and the First Amended Master Complaint against the Retailer Defendants. The

First Amended Master Complaints do not constitute a waiver or dismissal of any actions or claims asserted in those individual actions, and no Plaintiff relinquishes the right to amend his or her individual claims to include additional claims as discovery proceeds and as the facts or other circumstances may warrant.

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INTRODUCTION

1. For years, Defendant JJCI has willfully ignored and attempted to silence the science that prenatal ingestion of Tylenol can cause ASD and ADHD in children. The Tylenol labels contain no warning that there is any sort of risk of ASD or ADHD if a woman ingests the drug while pregnant. Instead, JJCI has marketed the drug as a completely safe pain medication for pregnant women. This campaign has been effective, as approximately 65% of pregnant women take some form of acetaminophen while pregnant, and most do so electively for minor aches and pains.

2. But acetaminophen, the sole active ingredient of the Tylenol products at issue in this MDL, can cause ASD and/or ADHD in children when ingested by their mothers while pregnant. To date, at least 26 epidemiological studies have shown positive associations between prenatal use of acetaminophen and ASD and/or ADHD. Critically, at least sixteen of those studies specifically investigated whether a dose-response association exists. They *all* found one.

3. Scientists designed several of the studies to address certain limitations associated with observational studies. For instance, a common limitation of observational studies is that they rely on patients to self-report their exposure to the drug or toxin in question, which creates a risk of recall bias. To control for this, one peer-reviewed study published in a prominent scientific journal examined maternal umbilical cord blood samples to assess acetaminophen levels.[2] The study stratified the results into tertiles to evaluate the risk of various levels of exposure. The results showed that women with children in the top one-third acetaminophen levels, compared to those in

[2] Yuelong Ji et al., *Association of Cord Plasma Biomarkers of In Utero Acetaminophen Exposure With Risk of Attention-Deficit/Hyperactivity Disorder and Autism Spectrum Disorder in Childhood*, 77 JAMA Psychiatry 180 (2020).

the lowest tertile, suffered a 3.62 times increased risk of giving birth to a child later diagnosed with ASD and a 2.86 times increased risk of giving birth to a child later diagnosed with ADHD.

4. The scientific evidence spurred over ninety scientists to sign a consensus statement issued in September 2021 about the causal relationship between prenatal use of acetaminophen and ASD and ADHD. It is unusual for such a broad coalition of scientific experts to sign a single statement. The authors concluded: "the combined weight of animal and human scientific evidence is strong enough for pregnant women to be cautioned by health professionals against [acetaminophen's] indiscriminate use, both as a single ingredient and in combination with other medications."[3] Other researchers have subsequently reviewed the medical and scientific literature, finding that "prenatal exposure to paracetamol causes statistically significant risks of developmental delays, attention deficit hyperactivity disorder, and a subtype of autism spectrum disorder (ASD) associated with hyperkinetic behavior."[4]

5. JJCI has paid no heed to the scientific facts. JJCI continues to promote Tylenol's safety to pregnant women and has taken no steps to update its labels to warn of its risks.

6. Drugs regulated by the Food and Drug Administration ("FDA") are replete with examples of drug labels that provide complete information regarding risks even when the underlying science—unlike here—is not fully settled. These labels reflect the aims of the regulatory system, which recognizes states' authority to require warnings to apprise consumers of certain risks. Pregnant women should be provided with complete information so that they can make informed decisions regarding the risks to which they expose their unborn children.

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[3] Ann Z. Bauer et al., *Paracetamol Use During Pregnancy—A Call for Precautionary Action*, 17 Nature Revs. Endocrinology 757, 763 (2021).

[4] Esha Patel et al., *The Safety of Pediatric Use of Paracetamol (Acetaminophen): A Narrative Review of Direct and Indirect Evidence*, Minerva Pediatrics, July 2022, https://doi.org/10.23736/S2724-5276.22.06932-4.

7. But JJCI has deprived Plaintiffs of the right to make that choice. Mothers relied on the Tylenol label when deciding to consume the drug while pregnant. Had the Tylenol label contained *any* warning of acetaminophen's ASD/ADHD risk, Plaintiff mothers would have reduced or eliminated Tylenol consumption while pregnant, preventing their Plaintiff Children from developing incurable neurodevelopmental disorders.

8. J&J, while making JJCI stay silent on the risks of developing ASD and ADHD, has simultaneously sought to profit on the ASD epidemic through its other subsidiary, Janssen Research & Development, LLC ("Janssen"). Janssen operates the Janssen Autism Knowledge Engine ("JAKE"), which caregivers use to track ASD patients' data as well as their mother's data and then submit that data to a data warehouse managed by Janssen. Notably, the JAKE application does not track a mother's use of Tylenol—as J&J has no interest in further validating that causal association. Through the JAKE application, J&J hopes to develop ASD treatments and profit off the epidemic J&J has helped create.

9. Plaintiffs consist of children who have developed ASD and/or ADHD as a result of their mothers' use of Tylenol while pregnant, as well as the children's parents and/or guardians. The Tylenol products at issue consist only of pure-acetaminophen products, such as Tylenol Regular®, Tylenol Extra Strength®, and Tylenol Extra Strength Rapid Release Gels®.[5]

10. JJCI breached its duty to adequately warn consumers of the risks of developing ASD and/or ADHD when exposed to Tylenol in utero. JJCI continues to breach it every day with every Tylenol product sold without warning about the increased ASD/ADHD risks associated with product use, ensuring that future mothers and children will receive the same sorts of devastating

[5] This product list is not meant to be exhaustive, and Plaintiffs reserve the right to plead the specific acetaminophen-only product ingested in their Short Form Complaint.

diagnoses as Plaintiffs. To compensate them for their losses and to deter future misconduct, Plaintiffs bring failure to warn, design defect, negligence, negligent misrepresentation by omission, and breach of implied warranty claims against JJCI.

THE PARTIES

11. Plaintiffs in these individual actions are citizens/and or residents of the United States. Plaintiffs include those individuals who have suffered personal injuries in the form of ASD or ADHD as a result of their mothers' prenatal ingestion of acetaminophen while pregnant with Plaintiffs (hereinafter, "Plaintiff Children").

12. Plaintiffs also include guardians, as set forth in Federal Rule Civil Procedure 17(c), of Plaintiff Children, described *supra* ¶ 11, who are also minors.

13. Plaintiffs further include parents or other guardians of Plaintiff Children, described *supra* ¶ 11, who have suffered personal injuries in their own right as a result of their children, grandchildren, or wards suffering from ASD and/or ADHD as a result of prenatal exposure to acetaminophen (hereinafter, "Plaintiff Parents," and collectively, Plaintiff Children and Plaintiff Parents shall be referred to as "Plaintiffs").

14. Defendant Johnson & Johnson Consumer Inc. f/k/a McNeil-PPC, Inc. ("JJCI") is, and at all relevant times was, a New Jersey corporation with its principal place of business in the state of New Jersey.

15. At all relevant times, and based on information and belief, JJCI was engaged in the business of researching, developing, manufacturing, formulating, marketing, testing, promoting, licensing, selling, and/or distributing Tylenol.

16. JJCI is a wholly-owned subsidiary of Johnson & Johnson, Inc.

17. At all relevant times, JJCI regularly transacted, solicited and conducted business in all fifty states of the United States.

JURISDICTION & VENUE

18. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a). In each of the actions, there is complete diversity among Plaintiffs and JJCI and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

19. Pursuant to the Transfer Orders of the Judicial Panel on Multidistrict Litigation, venue in actions sharing common questions with the initially transferred actions is proper in this Court for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407.

20. Each Plaintiff's proper venue under 28 U.S.C. § 1391 will be identified in each Plaintiff's individual Short Form Complaint.

21. At all times alleged herein, JJCI was authorized to conduct or engage in business within each of the States and Territories of the United States and supplied Tylenol within each of the States and Territories of the United States. JJCI received financial benefit and profits from designing, manufacturing, testing, marketing, labeling, packaging, handling, distributing, storing, and/or selling Tylenol, either directly or through a subsidiary, within each of the States and Territories of the United States.

22. JJCI has derived revenue from the sale of Tylenol and has significant contacts in each of the States and Territories of the United States, such that personal jurisdiction would be proper in any of them.

FACTUAL ALLEGATIONS

A. The Development of Acetaminophen.

23. Acetaminophen—or paracetamol, as it is known throughout Europe and much of the rest of the world—was first discovered in the latter half of the 19th century.

24. In the early 1950s, Robert McNeil—a graduate of Yale University and the Philadelphia College of Pharmacy and Science—led the research department at his family's small drug company. At a drug-industry conference, he found out about acetaminophen, which had been sold as a headache remedy in other countries.[6]

25. McNeil Laboratories capitalized on the bubbling concern over aspirin's side effects—upset stomachs, ulcers, and impairment of normal blood clotting—to launch acetaminophen as a safe and effective alternative for treating pain and fever. In 1955, McNeil Laboratories—an entity that would later become part of the Johnson & Johnson pharmaceutical empire—obtained FDA approval and began distributing a branded single-ingredient product called Tylenol Elixir for Children, an aspirin-free pain reliever and fever reducer. Its active ingredient was acetaminophen.[7] The brand name "Tylenol" was a derivative of a combination of letters found in the chemical name for acetaminophen:

N-aceTYL-p-aminophENOL.[8]

26. Tylenol was marketed directly to physicians and pharmacists and, at the time, was available by prescription only. McNeil Laboratories' initial strategy was to offer Tylenol as a

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[6] Stephen Miller, *Creator of Tylenol "For Little Hotheads"*, Wall St. J. (May 26, 2010), https://www.wsj.com/articles/SB10001424052748704026204575266780552207418.

[7] Natasha Singer, *Robert L. McNeil Jr., Chemist Who Introduced Tylenol, Dies at 94*, N.Y. Times (June 3, 2010), https://www.nytimes.com/2010/06/04/business/04mcneil.html.

[8] McNeil Consumer Healthcare Company, *History of TYLENOL*, http://www.nancywest.net/pdfs/McNeilConsumerHealthcareCompany.pdf.

remedy for children, and it sold the drug in a package modeled after a fire engine along with a slogan pitching the product "for little hotheads."[9] By 1960, the drug was available without a prescription, or "over-the-counter," and was marketed for use by children and adults alike.[10]

27. Since that time, acetaminophen has become one of the most widely used drugs in the world.

28. A 2006 survey found that acetaminophen was the most commonly used drug among adults in the United States, with 19% of adults reporting that they used the drug during a particular week.[11] J&J's July 2013 earnings call reported that McNeil's over-the-counter ("OTC") drug revenue had skyrocketed by 26%, identifying Children's Tylenol as one of the top two brands in OTC children's pain relief.[12] The same call reported that Extra Strength Tylenol had doubled its market share during the first half of 2013, cementing its status as America's No. 1 OTC adult pain reliever.[13]

29. Acetaminophen has long been marketed as the safest over-the-counter pain-relieving and fever-reducing treatment available for pregnant women.[14] In the United States, acetaminophen is estimated to be used by up to 65% of women during pregnancy.[15]

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[9] Miller, *supra* note 6.
[10] Singer, *supra* note 7.
[11] *Patterns of Medication Use in the United States*, Slone Epidemiology Ctr. at Bos. Univ. (2006), https://www.bu.edu/slone/files/2012/11/SloneSurveyReport2006.pdf (last visited Dec. 13, 2022).
[12] *Use Only As Directed*, ProPublica (Sept. 20, 2013), https://www.propublica.org/article/tylenol-mcneil-fda-use-only-as-directed.
[13] *Id.*
[14] *ACOG Response to Consensus Statement on Paracetamol Use During Pregnancy*, Am. Coll. of Obstetricians & Gynecologists (Sept. 29, 2021), https://www.acog.org/news/news-articles/2021/09/response-to-consensus-statement-on-paracetamol-use-during-pregnancy ("ACOG and obstetricians-gynecologists have always identified acetaminophen as one of the only safe pain relievers for pregnant individuals during pregnancy.").
[15] *See* Bauer et al., *supra* note 3, at 758.

B. Overview of Regulatory Framework.

30. Most federal regulation of pharmaceuticals is conducted pursuant to the Food, Drug, and Cosmetic Act ("FFDCA") (21 U.S.C. §§ 301 et seq.), with the FDA as the principal regulator. At a high level, the goal of FDA's regulation of drugs is to ensure the safety and effectiveness of pharmaceuticals for consumers.

31. Two regulatory pathways exist to bring an OTC—that is, non-prescription—drug to market: the New Drug Application ("NDA") process and the OTC Drug Review process. The latter is also known as the monograph system.

32. The NDA process regulates the approval for marketing and sale of new pharmaceuticals, such as name-brand drugs like Xanax or Lipitor. Generic-brand drugs are governed by the corollary Abbreviated New Drug Application, or "ANDA," process.

33. The monograph system, by contrast, is not for new OTC drugs. Established in 1972, the monograph system was designed to regularize the marketing and sale of drugs that were already being marketed before May 11, 1972. For monograph drugs, a drug-specific pre-approval process was not necessary.

34. Acetaminophen is governed by the monograph system. As set forth further below, there are meaningful differences between the NDA process and the monograph system.

(a) The NDA Process

35. The NDA process is heavily regulated and requires FDA preapproval of any drug label before a drug can be brought to the market.[16]

[16] 21 U.S.C. §§ 355(a) ("No personal shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."); 355(b)(1) (enumerating the materials required to be submitted with such an application, including "(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use; (ii) a

36. FDA's approval of an NDA before the drug is brought to market includes approval of the *exact text* of the proposed label.[17]

37. Once FDA issues a formal approval letter, a drugmaker can begin marketing the drug using *only* the exact text from the approved label. And once that approval occurs, the drugmaker cannot unilaterally make most types of label changes. Indeed, federal regulations prohibit most types of changes to an NDA label without FDA preapproval of a supplemental application.[18]

38. There is an exception to this general rule for NDA drugs called the "changes being effected"—or CBE—regulation.[19] Pursuant to the CBE, an NDA holder may unilaterally *strengthen* the label's warnings and precautions—without FDA preapproval—based on "newly

full list of the articles used as components of such drug; (iii) a full statement of the composition of such drug; (iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (v) such samples of such drug and of the articles used as components thereof as the Secretary may require; (vi) specimens of the labeling proposed to be used for such drug; (vii) any assessments required under section 355(c) of this title; and (viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug. . . .").

[17] *See* 21 U.S.C. § 355; 21 C.F.R. § 314.105(b) ("FDA will approve an NDA and issue the applicant an approval letter on the basis of draft labeling if the only deficiencies in the NDA concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.").

[18] 21 C.F.R. § 314.70(b) (prohibiting most types of changes to an NDA label without FDA preapproval of a supplemental application).

[19] 21 C.F.R. § 314.70(c)(3).

acquired information."[20] If FDA does not believe the CBE regulation has been satisfied, however, it can subsequently reject that labeling change.[21]

39. ANDA manufacturers—i.e., those who manufacture generic drugs comparable in dosage, form, strength, route of administration, quality, performance characteristics, and intended use to a name-brand drug—have even less latitude to change their labels without FDA preapproval. ANDAs are approved after FDA determines that the generic product matches exactly the product of an NDA holder in all relevant respects. By regulation, an ANDA holder's warning label must match the NDA holder's label verbatim.[22]

[20] 21 C.F.R. § 314.70(c)(6)(iii) ("The agency may designate a category of changes for the purpose of providing that, In the case of a change in such category, the holder of an approved NDA may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change. These changes include, but are not limited to . . . [c]hanges in the labeling to reflect newly acquired information. . . .").

[21] *Id.*

[22] 21 U.S.C. §§ 355(j)(2)(A)(v) ("An abbreviated application for a new drug shall contain . . . information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;"); 355(j)(4)(G) ("Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds . . . information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph 2(C) or because the drug and the listed drug are produced or distributed by different manufacturers;"); 21 C.F.R. §§ 314.94(a)(8) (ANDA applications must include copies of approved labeling, copies of proposed labeling, a statement on the proposed labeling, and a comparison of approved and proposed labeling); 314.127(a)(7) (FDA will refuse to approve an ANDA for a new drug under section 505(j) of the FFDCA if "[i]nformation submitted in the ANDA is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the ANDA except for changes required because of differences approved in a petition [] or because the drug product and the reference listed drug are produced or distributed by different manufacturers or because aspects of the listed drug's labeling are protected by patent, or be exclusivity, and such differences do not render the proposed drug product less safe or effective than the listed drug for all remaining, nonprotected conditions of use.").

40. This means that, under the NDA system, ANDA holders cannot avail themselves of the CBE regulation to unilaterally strengthen warnings or precautions even in the face of new information.

(b) The Monograph System

41. The monograph system operates differently. Marketers of monograph OTC drugs do not submit a premarketing application with a label that FDA then approves.[23]

42. Indeed, FDA never even reviews a monograph's drug label. There is no monograph equivalent to 21 C.F.R. § 314.0(b) that requires FDA preapproval to alter an OTC label after a monograph drug is on the market, so of course there is no CBE exception to that nonexistent general rule.[24]

43. Instead, under the monograph system, FDA issues a comprehensive regulation—a monograph—for each therapeutic class of OTC drugs, setting out each drug's FDA-approved active ingredients and then identifying the conditions under which the drugs are generally recognized as safe and effective.[25] This system regulates by class of drugs rather than by individual drug. Under the monograph system, there are no "generic" drugs operating under a modified regulatory framework under the monograph system. Different brand names, such as Tylenol or Equate™, are governed by the same rules. The makers of each brand are equally deemed "marketers" under the applicable regulations.[26]

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[23] *See* Over-The-Counter Human Drugs; Labeling Requirements, 64 Fed. Reg. 13,254, 13,271 (Mar. 17, 1999) ("Products that are marketed under an OTC drug monograph are not required to submit labeling to the agency for preapproval.").
[24] *Compare* 21 C.F.R. § 330.1 *with* 21 C.F.R. § 314.70(b).
[25] *Id.*
[26] 21 C.F.R. § 330.13(b)(2) ("Marketing of such a product with a formulation or labeling not in accord with a proposed monograph or tentative final monograph also may result in regulatory action against the product, the marketer, or both.").

44. As a consequence, all OTC drug marketers are treated equally and have the ability to unilaterally change their labels. There is no distinction under the regulatory regime between, for instance, JJCI, the marketer of Tylenol, and Walmart, Inc., ("Walmart") the marketer of Equate™. Both sets of marketers have the duty to update the drug's label to account for risks under the regulatory regime and state law.

45. One distinction between the monograph and NDA regulatory schemes is particularly salient. Because a drug's over-the-counter monograph does not specify the exact label that must be used with respect to a particular drug, marketers must use their professional judgment to create packaging that complies with FDA's regulations. Thus, unlike with the NDA system, marketers of monograph drugs can unilaterally make changes to the warning label as long as those changes do not conflict with the warnings required by applicable regulations that carry the force of law.

(c) The Acetaminophen Monograph

46. In accord with this system, the monograph that governs acetaminophen addresses the internal analgesic, antipyretic, and antirheumatic class of drugs. It states at the outset that "[a drug like acetaminophen] is generally recognized as safe and effective and is not misbranded if it meets each condition in this [monograph] in addition to each of the general conditions established in § 330.1 of this chapter."[27]

47. The acetaminophen monograph then goes on to outline the applicable conditions that the drug is required to satisfy. Some of these conditions are stated in terms of a floor—

[27] Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for the Over-the-Counter Human Use; Tentative Final Monograph, 53 Fed. Reg. 46,204, 46,255 ("Acetaminophen Monograph").

minimal requirements with no limitations on what can be added. Others are stated in terms of a ceiling—requirements that cannot be supplemented.

48. Absent from the monograph's warnings section is anything suggesting that the required warnings are *exclusive*. Accordingly, marketers retain the regulatory freedom to provide *additional*, truthful warnings that do not contradict the warnings required by federal law. And, in fact, the onus is on marketers to use their professional judgment to create packaging that complies with federal regulations.

49. L.N.K. International, Inc. ("LNK"), a distributor of acetaminophen to some retailer defendants in this litigation, such as CVS, Rite Aid, Walgreens, and Walmart, admitted this point in a complaint regarding insurance coverage stemming from the lawsuits in this MDL.[28] In that pleading, LNK stated "[b]ecause a drug's OTC monograph does not provide the specific label that must be used with respect to a given drug, LNK must use its professional judgment to create packaging that complies with FDA regulations."[29]

50. Although nothing has prevented JJCI from doing so, it has not included any warnings on its Tylenol labels regarding the risk that prenatal ingestion of acetaminophen may cause ASD or ADHD.

(d) Acetaminophen Was Marketed Under a Tentative Monograph Until 2021

51. A monograph must proceed through multiple steps before it carries the force of law. As established in 21 C.F.R. § 330.10, the process to a final monograph includes four main steps: (1) a review by a panel of qualified experts that then recommends the conditions under which the drug can be used; (2) publication of the expert panel's recommendations in the form of a proposed

[28] *See L.N.K. Int'l, Inc. v. Continental Casualty Co.*, No. 22-cv-5184 (E.D.N.Y.), Dkt. 1.
[29] *Id.* at ¶ 17.

rule in the Federal Register for public comment; (3) FDA review of the comments on the experts' proposed rule and publication of a tentative final monograph (acetaminophen) with a second opportunity for comments on the Tentative Final Monograph ("TFM"); and (4) publication of the final monograph, which includes FDA's findings on when a drug is considered to be generally safe and effective for use.[30]

52. On November 16, 1988, FDA reached step three for OTC drugs containing acetaminophen.[31] For the next thirty years, OTC drugs containing acetaminophen operated under the TFM, which had the "legal status . . . of a proposed rule."[32]

53. Congress changed the status of TFMs—including the acetaminophen TFM—with the CARES Act in March 2020.[33] It provided that a "tentative final monograph . . . shall be deemed to be a final administrative order."[34]

C. JJCI Manufactures and Sells Tylenol and Has Control Over the Product and Labeling.

54. J&J has sold and marketed Tylenol since 1959, when it acquired McNeil Laboratories.

55. From at least 1970 until 2015, McNeil-PPC, Inc., a wholly owned subsidiary of J&J, designed, manufactured, packaged, labeled, marketed, sold and/or distributed Tylenol.

56. In 2015, McNeil-PPC, Inc. merged with several other J&J companies and became JJCI.

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[30] *See generally* 21 C.F.R. § 330.10.
[31] Acetaminophen Monograph, 53 Fed. Reg. at 46,248.
[32] *Id.* at 46,204.
[33] *See* Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281, 447 (Mar. 27, 2020).
[34] *See id.*

57. From that date through the date of this filing, JJCI has designed, manufactured, packaged, labeled, marketed, sold and/or distributed Tylenol.

58. Since 1987, McNeil Consumer Products Company, a division of McNeil-PPC, Inc. and now, based on information and belief, JJCI, has designed, manufactured, packaged, labeled, marketed, and/or distributed Tylenol.

59. At all relevant times, and since at least 1970, J&J has designed, manufactured, packaged, labeled, marketed, and/or distributed Tylenol in conjunction with McNeil-PPC, Inc., McNeil Consumer Products Company, and JJCI.

60. Based on information and belief, J&J has maintained and exercised ultimate control over Tylenol, including over the labeling and marketing of Tylenol at all relevant times hereto and since at least 1970.

61. The Tylenol products that are the subject of this litigation consist of those products with acetaminophen as the sole active ingredient.

D. Overview of ASD and ADHD.

62. ASD is a serious neurological disorder that typically manifests its symptoms early in childhood and can require lifelong care.[35]

63. Although the symptoms of ASD are wide-ranging, they generally include aberrant behavior and difficulty with social interaction and communication.[36] Many children with ASD also suffer from intellectual disability, with an IQ score below 70, and/or ADHD.[37]

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[35] *See Autism*, World Health Org. (Mar. 30, 2022), https://www.who.int/news-room/fact-sheets/detail/autism-spectrum-disorders.

[36] *Id*.

[37] Am. Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders* 58–59 (5th ed. 2013); *see also* Autism & Developmental Disabilities Monitoring (ADDM) Network, *Community Report on Autism* 10, 48 (2021), https://bit.ly/3HePIbz ("2021 Autism Report").

64. The American Psychiatric Association previously provided five possible diagnoses for autistic conditions, ranging from Asperger's syndrome on the milder end to autistic disorder on the severe end.[38] The fifth and current edition of the Association's *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-5") now provides for a single diagnosis, Autism Spectrum Disorder, with three levels of severity.[39]

65. Children with Level 1 autism, the mildest form, require some support in daily life.[40] These children can often speak in full sentences but still have trouble initiating social interactions, reading nonverbal cues, and engaging in back-and-forth conversation.[41] Making friends might not come easily, and an inflexibility of behavior can make it difficult to switch between activities.[42] These children might also experience problems with organization and planning that limit their independence.[43]

66. Children with Level 2 autism require substantial support in daily life.[44] These children have more obvious problems with communication, often speaking in simple sentences and struggling with nonverbal communication.[45] They also tend to have narrow interests and to engage in odd, repetitive behaviors, which further limits their social interactions and their ability to function in various contexts.[46]

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[38] Am. Psychiatric Ass'n, *supra* note 37, at 51.
[39] *Id.* at 52.
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] *Id.*
[46] *Id.*

67. Children with Level 3 autism, the severest form, require very substantial support in daily life.[47] These children have significant difficulty expressing themselves and will often be entirely nonverbal.[48] They might interact with others only in response to direct approaches.[49] And they will exhibit extreme inflexibility, engaging in repetitive behaviors and feeling great distress when changing focus, which impedes their ability to function in everyday situations.[50]

68. ASD can be reliably diagnosed by age 2 and is sometimes detectable earlier.[51] But diagnosis is based on observation; there is no medical test for ASD.[52] Many children are diagnosed after age 4.[53]

69. The disorder can go undiagnosed until much later in life, even into adulthood.[54]

70. Treatments for ASD include varying degrees of behavioral management therapy, cognitive behavior therapy, joint attention therapies, physical therapy, speech-language therapy, occupational therapy, social skills training, and medication.[55]

71. Treatment for ASD lasts a lifetime, and there is no cure for the condition.[56]

72. According to one report, as of 2018, an estimated 2.3% of 8-year-old American children, or 1 in 44, have been identified with ASD.[57]

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[47] *Id*.
[48] *Id*.
[49] *Id*.
[50] *Id*.
[51] *Id.* at 55; 2021 Autism Report, *supra* note 37, at 36.
[52] 2021 Autism Report, *supra* note 37, at 19.
[53] *Id.* at 9–10.
[54] *See generally* Steven D. Stagg & Hannah Belcher, *Living with Autism Without Knowing: Receiving a Diagnosis in Later Life*, 7 Health Psych. & Behav. Med. 348 (2019).
[55] Laura C. Politte et al., *Evidence-Based Treatments for Autism Spectrum Disorder*, 2 Current Treatment Options in Psychiatry 38 (2015).
[56] *Autism*, World Health Org., *supra* note 35.
[57] *See* 2021 Autism Report, *supra* note 37, at 9.

73. By comparison, the World Health Organization ("WHO") currently estimates that approximately 1 in 100 children has ASD worldwide, making childhood autism over two times more prevalent in the United States than the global average.[58]

74. Like ASD, ADHD is a neurological disorder that typically begins in childhood, persists through adulthood and has become more prevalent among American children over time.[59]

75. ADHD is now one of the most common neurodevelopmental disorders among American children.[60]

76. This estimate reflects a rise of several percentage points since the first national ADHD survey was conducted in 1997.[61]

77. ADHD can result in multiple abnormal behavioral outcomes, including hyperactivity, impulsiveness, and/or an inability to focus.[62]

78. These symptoms correlate with an array of problems in school, work, relationships, and mental and physical health.[63] Compared to children without ADHD, children with ADHD have been found to attain lower academic achievement;[64] are more likely to suffer from

[58] *See Autism*, World Health Org., *supra* note 35.
[59] *See What Is ADHD?*, Ctrs. for Disease Control & Prevention (Aug. 9, 2022), https://www.cdc.gov/ncbddd/adhd/facts.html.
[60] *Id*.
[61] *See ADHA Throughout the Years*, Ctrs. for Disease Control & Prevention (Aug. 9, 2022), https://www.cdc.gov/ncbddd/adhd/timeline.html.
[62] *What is ADHD?*, *supra* note 61.
[63] *See PALS Publications*, Youth & Family Rsch. Program, Dep't of Psychiatry, Univ. of Pittsburgh (Oct. 3, 2022), http://yfrp.pitt.edu/pals/publications (collecting publications based on the Pittsburgh ADHD Longitudinal Study (PALS)).
[64] *See* K.M. Kent et al., *The Academic Experience of Male High School Students With ADHD*, 39 J. Abnormal Child Psych. 451 (2011).

depression;[65] engage in more substance abuse;[66] risky sexual conduct;[67] and other unsafe activities.[68] One study found that males with a history of ADHD are expected to earn $1.27 million less over their lifetimes than controls without ADHD, potentially retiring with 75% lower net worth.[69]

79. Treatments for ADHD include speech and behavioral therapies, occupational therapy, individualized educational assistance, and medication.[70] As of 2014, almost 9 in 10 children with ADHD were receiving some form of school support, including school accommodations or help in the classroom.[71] As of 2016, 77% of children with ADHD were receiving some form of treatment, whether medication, behavioral treatment, or both.[72]

80. Just as with ASD, treatment for ADHD lasts a lifetime, and there is no cure for it.[73]

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[65] *See* M.C. Meinzer et al., *Does Childhood Attention-Deficit/Hyperactivity Disorder (ADHD) Predict Levels of Depressive Symptoms During Emerging Adulthood?*, 44 J. Abnormal Child Psych. 787 (2016).
[66] *See* Brooke S.G. Molina & William E. Pelham Jr., *Childhood Predictors of Adolescent Substance Use in a Longitudinal Study of Children with ADHD*, 112 J. Abnormal Psych. 497 (2003).
[67] *See* Kate Flory et al., *Childhood ADHD Predicts Risky Sexual Behavior In Young Adulthood*, 35 J. Clinical Child & Adolescent Psych. 571 (2006).
[68] *Attention-Deficit/Hyperactivity Disorder in Children and Teens: What You Need to Know*, Nat'l Inst. Mental Health (2021), https://www.nimh.nih.gov/health/publications/attention-deficit-hyperactivity-disorder-in-children-and-teens-what-you-need-to-know.
[69] *See* William E. Pelham III et al., *The Long-Term Financial Outcome of Children Diagnosed with ADHD*, 88 J. Consulting & Clinical Psych. 160 (2020).
[70] *Attention-Deficit/Hyperactivity Disorder in Children and Teens: What You Need to Know*, *supra* note 70.
[71] *See Data & Statistics About ADHD*, Ctrs. for Disease Control & Prevention (Aug. 9, 2022), https://www.cdc.gov/ncbddd/adhd/data.html.
[72] *See id*.
[73] Mark L. Wolraich et al., *Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents*, 144 Pediatrics 9 (2019).

E. Acetaminophen Causes ASD and ADHD.

81. For years, the scientific evidence has shown that acetaminophen can cause ASD and ADHD in children whose mothers ingested the drug while pregnant and that the more acetaminophen ingested, the greater the risk.

82. Parental awareness and changes in diagnoses do not account for the rapid rise in ASD and ADHD diagnoses, *see supra* ¶¶ 74, 75, 78, or the prevalence in the United States as compared to the rest of the world.

83. A comparison between the United States and Cuba is instructive. The total estimated percentage of the population with ASD *is 298 times higher* in the United States than in Cuba.[74] Critically, unlike in the United States, where acetaminophen is available over the counter and is regularly taken by pregnant women, the drug requires a prescription in Cuba and is not regularly prescribed for use by pregnant women.[75]

84. Since 2013, scientists in at least six European birth cohort studies, examining over 70,000 mother-child pairs, have shown an association between prenatal use of acetaminophen and ASD and ADHD. A birth cohort study follows a group of people that were born at a similar date or period of time. By following a group over time and collecting information at regular intervals, a birth cohort study gives the authors particular insight into how variables, including prenatal exposures to chemicals, affect babies and children as they age.

85. In one of those studies, published in a well-known, peer-reviewed publication in 2013, scientists undertook an expansive sibling-controlled analysis of 48,631 children from the

[74] William Shaw, *Evidence that Increased Acetaminophen Use in Genetically Vulnerable Children Appears To Be a Major Cause of the Epidemics of Autism, Attention Deficit with Hyperactivity, and Asthma*, 2 J. Restorative Med. 14, 15 (2013).
[75] *See id*. at 15–18 (2013).

Norwegian Mother and Child Cohort Study whose mothers had returned a 3-year follow up questionnaire.[76] Between 1999 and 2008, all pregnant Norwegian women were eligible to participate in the study, and 38.7% of pregnant women participated.[77] The study population included 2,919 same-sex sibling pairs who were used to adjust for familiar and genetic factors.[78] During the study, the mothers submitted two questionnaires around gestational weeks 17 and 30 reporting their medication use during the pregnancy and a follow-up questionnaire three years post-birth.[79] The study cohort was also linked to the Medical Registry of Norway, which contained detailed medical information regarding the child.[80]

86. The study authors concluded that "paracetamol use for more than 28 days during pregnancy was associated with adverse outcomes for gross motor and communication development, behavior and activity at 4 years of age. In contrast, we found no association between ibuprofen on the same neurodevelopmental outcomes, which suggests a specific effect of paracetamol less likely to be confounded by indication."[81] "In clinical terms, the[ ] results suggest that exposure to paracetamol for more than 28 days during fetal life increases the risk of adverse psychomotor and behavioral outcomes by almost 70% and doubles the risk of language problems in 3-year-old children."[82] Ultimately, the authors concluded that "[c]hildren exposed to long-term use of paracetamol during pregnancy had substantially adverse developmental outcomes at 3 years of age."[83]

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[76] Ragnhild Eek Brandlistuen et al., *Prenatal Paracetamol Exposure and Child Neurodevelopment: A Sibling-Controlled Cohort Study*, 42 Int'l J. Epidemiology 1702 (2013).
[77] *Id.* at 1703.
[78] *Id*.
[79] *Id*.
[80] *Id.*
[81] *Id.* at 1710.
[82] *Id.* at 1711.
[83] *Id.* at 1702.

87. In 2014, a peer-reviewed, prospective study was published in JAMA Pediatrics that assessed the association between prenatal use of acetaminophen during pregnancy and behavioral issues, hyperkinetic disorders (HKD, a severe form of ADHD), and ADHD medications.[84] The study found that acetaminophen use during pregnancy was associated with a higher risk for all three outcomes.[85] For the study, the authors conducted three telephone interviews with the mothers (two during pregnancy and one six months after birth) and administered a standardized behavioral questionnaire to the caregiver when the child was seven years old.[86] Notably, the study detected a statistically significant dose-response relationship, a critical feature of a causal relationship: "[s]tronger associations were observed with use in more than 1 trimester during pregnancy, and exposure response trends were found with increasing frequency of acetaminophen use during gestation for all outcomes."[87] "When women reported having used acetaminophen for 20 or more weeks during pregnancy, the risk of HKD diagnosis in children almost doubled (hazard ratio, 1.84; 95% CI, 1.39–2.45) . . . [.]"[88] A statistically significant dose-response relationship supports a causal relationship between exposure to acetaminophen and ADHD. The hazard ratio is defined as an instantaneous risk (i.e., given that the person has not yet had the event or be lost to follow-up at time t, what is the risk they will get the event at time t+1). It represents the ratio of the probability of an outcome in an exposed group to the probability of an outcome in an unexposed group. A confidence interval ("CI") determines the probability that the interval produced will contain the true parameter value. The authors concluded, "[u]sing prospective data from a well-

[84] Zeyan Liew et al., *Acetaminophen Use During Pregnancy, Behavioral Problems, and Hyperkinetic Disorders*, 168 *JAMA Pediatrics* 313 (2014).
[85] *Id.* at 313, 316–17.
[86] *Id.* at 314
[87] *Id.* at 313.
[88] *Id.* at 317.

designed large cohort of pregnant women with a long duration of follow-up and registry-based outcome assessment, we found that prenatal exposures to acetaminophen may increase the risk in children of receiving a hospital diagnosis of HKD or [taking] ADHD medication and of exhibiting ADHD-like behaviors, with higher use frequency increasing risk in an exposure-response manner."[89]

88. Another observational birth cohort study—this one from New Zealand—further solidified the causal relationship between acetaminophen and ADHD in 2014.[90] The study authors stated that they undertook the study to obtain more clarity in response to the "alarming" finding published by Liew in JAMA Pediatrics.[91] The prospective study examined use during pregnancy of acetaminophen, aspirin, antacids, and antibiotics in relation to behavioral difficulties and ADHD symptoms at ages 7 and 11 by parent reporting and "found that the children of mothers who used Acetaminophen during pregnancy were at increased risk of having symptoms of ADHD" and that their "findings strengthen the contention that acetaminophen exposure in pregnancy increase the risk of ADHD-like behaviors, as published by Liew et al."[92] Notably, the study found that there was "no association" between ADHD and the numerous other examined drugs used during pregnancy, including aspirin, antacids, and antibiotics.[93]

89. In 2016, another peer-reviewed study focused on 1,491 mothers/children enrolled in the Danish National Birth Cohort and prospectively recorded prenatal use of acetaminophen and

[89] *Id.* at 319.
[90] John M.D. Thompson et al., *Associations Between Acetaminophen Use during Pregnancy and ADHD Symptoms Measured at Ages 7 and 11 Years*, 9 PLOS ONE 1 (2014).
[91] *Id.* at 1.
[92] *Id* at 4.
[93] *Id.*

then assessed executive function when the children reached five years old.[94] The study concluded that "[t]he risks for subnormal overall attention or executive function were elevated with longer duration of paracetamol use during pregnancy."[95]

90. Later in 2016, scientists published a second peer-reviewed study focused on the Danish National Birth Cohort, which followed 64,322 children and mothers for an average of 12.7 years and obtained data regarding prenatal acetaminophen use during phone interviews during the 12th and 30th gestational week and 6 months after birth.[96] That study "found prenatal exposures to acetaminophen to be associated with elevated risk for ASD with hyperkinetic features."[97]

91. That same year, scientists published a prospective, confounder adjusted study of a Spanish birth cohort consisting of 2,644 mother-child pregnancy pairs to examine the causal association between acetaminophen and ASD and ADHD.[98] The scientists collected information regarding prenatal use of acetaminophen prospectively by interviewing the pregnant mothers at 12 and 32 gestational weeks.[99] All children were evaluated in-person by trained psychologists, computer-based measures, teacher-rated scales and specific symptom diagnostic tools for ADHD and ASD symptoms.[100] The results showed prenatal use of acetaminophen was associated with greater risk of ASD in males and showed a greater risk of ADHD in both sexes.[101] The authors

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[94] Zeyan Liew et al., *Paracetamol Use During Pregnancy and Attention and Executive Function In Offspring at Age 5 Years*, 45 Int'l J. Epidemiology 2009 (2016).
[95] *Id*. at 2009.
[96] Zeyan Liew et al., *Maternal Use of Acetaminophen During Pregnancy and Risk of Autism Spectrum Disorders in Childhood: A Danish National Birth Cohort Study*, 9 Autism Res. 951 (2016).
[97] *Id*. at 956.
[98] Claudia B. Avella-Garcia et al., *Acetaminophen Use in Pregnancy and Neurodevelopment: Attention Function and Autism Spectrum Symptoms*, 45 Int'l J. Epidemiology 1987 (2016).
[99] *Id*. at 1989.
[100] *Id*. at 1988–94.
[101] *Id*. at 1993–94.

noted that "[t]hese associations seem to be dependent on the frequency of exposure [to acetaminophen]."[102]

92. Yet another study published the same year attempted to assess the association between acetaminophen and neurodevelopmental disorders while addressing confounding factors such as genetics.[103] This study consisted of 14,541 pregnant women from the Avon Longitudinal Study of Parents and Children cohort in Bristol, England.[104] Maternal acetaminophen use was measured at 18 and 32 weeks of pregnancy.[105] Behavioral symptoms were collected by the mother's completing the Strengths and Difficulties Questionnaire, a child behavior screening questionnaire, when the child was 7 years old.[106] "In this study [the authors] [ ] demonstrated that children exposed prenatally to acetaminophen in second and third trimesters are at increased risk of multiple behavioral difficulties, including hyperactivity and conduct problems."[107]

93. In 2017, a study focused on the Norwegian Birth Cohort also attempted to assess the association between prenatal use of acetaminophen and ADHD while accounting for genetic factors.[108] The final sample included 112,973 children and their parents.[109] The study sent questionnaires at 18 weeks of gestation, later months of pregnancy, and after delivery.[110] The study then followed up with the children at 6 months old, 1.5 years, and 3 years old.[111] Even

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[102] *Id.* at 1988.
[103] *See* Evie Stergiakouli et al., *Association of Acetaminophen Use During Pregnancy With Behavioral Problems in Childhood: Evidence Against Confounding*, 170 JAMA Pediatrics 964 (2016).
[104] *Id*. at 965.
[105] *Id*.
[106] *Id*. at 965–66.
[107] *Id*. at 967.
[108] *See* Eivind Ystrom et al., *Prenatal Exposure to Acetaminophen and Risk of ADHD*, 140 Pediatrics 1 (2017).
[109] *Id*. at 1.
[110] *Id*. at 2.
[111] *Id*.

adjusting for confounders, the study found that "[l]ong-term maternal use of [APAP] during pregnancy is associated with ADHD in offspring."[112] Notably, the results from that study yielded a hazard ratio of 2.20 (95% CI 1.50–3.24) for developing ADHD when the mother ingested acetaminophen for 29 or more days while pregnant.[113] A 95% CI of 1.5 to 3.24 means that there is a 95% probability that the true association between acetaminophen exposure and risk of ADHD is between a 1.5-fold to 3.3-fold increased relative risk. Thus, the 2.20 hazard ratio in this study means that "[a]fter adjusting for familial risk for ADHD, indications of use, and acetaminophen use before pregnancy, long-term acetaminophen use during pregnancy is related to more than a twofold increase in risk for offspring ADHD."[114]

94. In 2018, a Swedish pregnancy cohort study was published that assessed prenatal acetaminophen exposure and language development in children at 30 months.[115] The study focused on delayed language development because it "is an early marker of impaired cognitive development."[116] Acetaminophen exposure was measured by maternal self-reporting and acetaminophen concentration in a urine sample taken at study enrollment.[117] The study results showed that the adjusted odds ratio for language delay in girls whose mothers reported taking more than 6 tablets was 5.92 (95% CI 1.10–31.94), and the odds ratio for females whose mothers' acetaminophen use was in the highest versus lowest quartile was 10.34 (95% CI 1.37–77.86).[118] An odds ratio represents the odds that an exposure has occurred given a particular outcome

[112] *Id.* at 7.
[113] *Id*. at 4.
[114] *Id.* at 1.
[115] C.G. Bornehag et al., *Prenatal Exposure to Acetaminophen and Children's Language Development at 30 Months*, 51 Eur. Psychiatry 98 (2018).
[116] *Id.* at 99.
[117] *Id.* at 98–99.
[118] *Id.* at 98.

compared to the odds of the exposure having occurred in the absence of that outcome.[119] There were no significant findings for male study participants.[120] The authors concluded that "[g]iven the prevalence of prenatal APAP use and the importance of language development, these findings, if replicated, would suggest that pregnant women should limit their use of this analgesic during pregnancy."[121]

95. In 2020, scientists published a peer-reviewed study in JAMA Psychiatry using data from the Boston Birth Cohort.[122] To avoid any potential limitations of relying on self-reporting, the study measured acetaminophen in maternal cord plasma samples obtained within 1 to 3 days postpartum.[123] The results were illuminating. The authors divided the cord groups into three groups or "tertiles" based on "acetaminophen burden."[124] "Compared with being in the first tertile, being in the second and third tertiles of cord acetaminophen burden was associated with higher odds of ADHD diagnosis . . . and ASD diagnosis."[125] The second and third tertiles had odds ratios for ASD of 2.14 (95% CI .93–5.13) and 3.62 (95% CI 1.62–8.60) respectively for ASD and odds ratios of 2.26 (95% CI 1.40–3.69) and 2.86 (95% CI 1.77–4.67) for the second and third tertiles for ADHD.[126]

96. In basic terms, this means that the study participants with the top third levels of acetaminophen in cord plasma suffered a 3.62 times increased risk of giving birth to a child later

[119] An odds ratio is not the same as a hazard ratio, but it is often used to approximate a hazard ratio.
[120] *Id*.
[121] *Id.*
[122] Yuelong Ji, *supra* note 2.
[123] *Id*. at 181.
[124] *Id.* at 182.
[125] *Id*. at 180.
[126] *Id*. at 186.

diagnosed with ASD and a 2.86 times increased risk of giving birth to a child later diagnosed with ADHD.

97. The study's authors further noted that "[s]ensitivity analyses and subgroup analyses found consistent associations between acetaminophen and ADHD and acetaminophen and ASD across strata of potential confounders, including maternal indication, substance use, preterm birth, and child age and sex."[127] Finally, the authors concluded that their "findings support previous studies regarding the association between prenatal and perinatal acetaminophen exposure and childhood neurodevelopmental risk and warrant additional investigations."[128]

98. Another peer-reviewed study, conducted at Columbia University, of neurodevelopmental risk was published in 2020 in JAMA Pediatrics. This study, too, sought to avoid maternal self-reporting or incomplete information regarding the quantity of acetaminophen ingested, in this case, by analyzing the child's meconium.[129] This approach allowed the study's authors to reliably know the baby's exposure to acetaminophen prior to birth because the exposure level can be measured in the first feces of a newborn infant.[130] In addition to the meconium analysis, this study tracked the children participants to assess whether there was a physician diagnosis of ADHD and undertook an MRI analysis of each study participant at 9 to 11 years.[131] Compared with no acetaminophen, detection of acetaminophen in meconium was associated with an increased odds ratio of ADHD of 2.43 (95% CI 1.41–4.21).[132] Notably, a dose-response

[127] *Id*. at 183.
[128] *Id*. at 188.
[129] Brennan H. Baker et al., *Association of Prenatal Acetaminophen Exposure Measured in Meconium With Risk of Attention-Deficit/Hyperactivity Disorder Mediated by Frontoparietal Network Brain Connectivity*, 174 JAMA Pediatrics 1073 (2020).
[130] *Id*. at 1074.
[131] *Id.* at 1075.
[132] *Id.* at 1073.

association was detected; each doubling of exposure increased the odds of ADHD by 10% (OR, 1.10; 95% CI, 1.02–1.19).[133] Children with acetaminophen detected in meconium also showed brain development with increased negative connectivity between frontoparietal and default mode network nodes to clusters in the sensorimotor cortices, which mediated an indirect effect on increased child hyperactivity.[134]

99. Significantly, the authors of the Columbia University study stated that their "results suggest that prior studies may have been biased toward the null by inaccurate maternal recall."[135] Bias toward the null is shorthand for bias toward the null hypothesis, i.e., a bias toward there not being an association when in fact there may be, meaning that those prior studies may have *understated* the association between acetaminophen and ADHD.[136]

100. All told, at least 26 separate epidemiological studies have identified positive associations with acetaminophen exposure during pregnancy and ASD or ADHD.[137] Sixteen of those studies specifically investigated whether a dose-response association exists, and they *all* found one: increased amounts and duration of exposure to acetaminophen increased the risk of neurodevelopmental disorders.[138] All studies have limitations, which is why scientists look for consistency when weighing the totality of the evidence. Taken as a whole, the studies represent a strong, consistent body of evidence that acetaminophen can and does cause ASD and ADHD.

101. The epidemiologic evidence is fortified by consistent animal studies, neuroscience studies, and empirical evidence that demonstrate viable biologic mechanisms by which

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[133] *Id*.
[134] *Id.*
[135] *Id.* at 1079.
[136] *Id*.
[137] *See* Bauer et al., *supra* note 3, at 762 (collecting studies).
[138] *See id*.

acetaminophen causes ASD and ADHD and impactful real-world effects.[139] This consistent epidemiologic, animal, neuroscience and empirical evidence that has led independent physicians and scientists to demand that women be warned about the dangerous effects acetaminophen can have on their unborn children.[140]

102. Based on the overwhelming scientific evidence, in September 2021 over ninety scientists signed a consensus statement published in *Nature Reviews Endocrinology*, calling for precautionary action over the use of acetaminophen during pregnancy.[141] *Nature Reviews Endocrinology* is a leading, highly regarded, peer-reviewed medical journal.

103. The scientists issued this "call to action" because of the serious safety concerns of continued acetaminophen use by pregnant women given the overwhelming evidence that acetaminophen use during pregnancy causes ASD and ADHD.[142] The authors concluded that "the combined weight of animal and human scientific evidence is strong enough for pregnant women to be cautioned by health professionals against its indiscriminate use, both as a single ingredient and in combination with other medications."[143]

104. The signatories of the consensus statement are highly respected and diverse. They work all over the world from Yale to the University of Copenhagen and many other institutions. They are comprised of professors in the fields of public health, neurology, biostatistics, molecular biology, epidemiology, molecular and reproductive toxicology, endocrinology, pediatrics,

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[139] Stephen Schultz et al., *Endocannabinoid System Dysregulation from Acetaminophen Use May Lead to Autism Spectrum Disorder: Could Cannabinoid Treatment Be Efficacious?*, 26 Molecules 1845 (2021).
[140] Although the researchers do not cite to the Federal Reference Manual on Scientific Evidence, their analysis clearly satisfies the causality assessment requirements set forth therein. *See* Federal Reference Manual on Scientific Evidence 597–606 (3rd ed. 2011).
[141] *See* Bauer et al., *supra* note 3, at 763.
[142] *Id.* at 762–63.
[143] *Id*. at 764.

embryology, translational medicine, physiology, obstetrics, reproductive medicine and many others.[144]

105. These distinguished professionals came together because the "disturbing increases in the number of children with cognitive, learning and/or behavioral problems" will continue to rise if women are not warned of acetaminophen's risks.[145]

F. Despite the Overwhelming Science, JJCI Has Never Warned Pregnant Mothers of the Dangers Associated with Taking Acetaminophen While Pregnant.

106. Following the publication of the 2013 Norwegian Mother and Child Cohort Study,[146] a spokesperson for J&J said Tylenol "has an exceptional safety profile. As the authors note in the study, there are no prospective, randomized controlled studies demonstrating a causal link between acetaminophen use during pregnancy and adverse effects on child development."[147] A randomized control study is exceedingly rare for a pregnant study population, so the J&J spokesperson sought to undermine the 2013 study by pointing to a lack of scientific evidence she knew would likely never exist. Moreover, once the risk of neurodevelopmental disorders was identified, performing a randomized controlled study might well be unethical.[148]

107. JJCI's pattern of deflection and silence has continued to the present day, and JJCI has otherwise taken no steps to warn pregnant women of the dangers associated with taking acetaminophen while pregnant.

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[144] *Id*. at Supplemental Materials.
[145] *Id.* at 757.
[146] Brandlistuen et al., *supra* note 76.
[147] Kathryn Doyle, *Too Much Tylenol in Pregnancy Could Affect Development*, REUTERS HEALTH (Nov. 22, 2013), https://www.reuters.com/article/us-too-much-tylenol-in-pregnancy-could-a/too-much-tylenol-in-pregnancy-could-affect-development-idUSBRE9AL15920131122.
[148] *Id*.

108. For instance, based on information and belief, JJCI ran this advertisement, "Mother's Day: Celebrating the Moms Who Care Without Limits," and reinforced its message that Tylenol is safe for pregnant women:

109. JJCI has the ability and the duty to update the Tylenol label to ensure that it provides adequate warnings to consumers.

110. Although the Tylenol labels warn of various risks, including at least one warning that is not required by federal law, *nothing* on the Tylenol label warns pregnant women that ingestion of acetaminophen while pregnant can cause ASD and/or ADHD.

111. An example of one of the current Tylenol labels is excerpted below:

112. Drug marketers, like JJCI, have voluntarily added warnings of other risks on numerous occasions based on much less conclusive evidence than pleaded *supra* ¶¶ 81–105.

113. Indeed, the more restrictive "changes being effected" regulation for NDA drugs requires a stronger warning when "there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established."[149] A marketer may voluntarily add a warning under this rule "when the evidence meets the standard set forth in this rule, even if

[149] *See* 21 C.F.R. § 201.57(c)(6)(i)

that evidence would not also support a higher evidentiary standard, such as a finding that there is a 'preponderance' of evidence that a product actually causes a particular kind of adverse event."[150]

114. That standard, which does not even apply to monograph drugs, is easily satisfied here.

115. Notably, JJCI has voluntarily added a skin allergy warning to the Tylenol label based on the FDA's informal guidance. That guidance is based on much less conclusive scientific evidence than that which shows acetaminophen causes ASD and ADHD.

116. In 2013, the FDA issued a drug safety communication warning of the association between acetaminophen and skin reactions, including Stevens-Johnson Syndrome ("SJS"), toxic epidermal necrolysis ("TEN"), and acute generalized exanthematous pustulosis ("AGEP").

117. In that drug safety communication, the FDA detailed that it issued the drug safety communication based on a review of the FDA Adverse Reporting System database, also known as FAERS, as well as a review of the medical literature, which the FDA searched "for evidence of an association between acetaminophen and Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP)."[151] The FDA's search of the FAERs database from 1969 to 2012 identified 91 cases of SJS/TEN and 16 cases of AGEP.[152]

118. The underlying medical literature for these skin reactions consisted of twenty-six observational studies, and the purpose of the vast majority of those studies was not to investigate

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[150] *See* Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,604 (Aug. 22, 2008).
[151] U.S. Food & Drug Admin., *FDA Drug Safety Communication: FDA Warns of Rare but Serious Skin Reactions with the Pain Reliever/Fever Reducer Acetaminophen* (Aug. 1, 2013), http://wayback.archive-it.org/7993/20170113072517/http:/www.fda.gov/downloads/Drugs/DrugSafety/UCM363052.pdf
[152] *Id.*

causation.[153] Of those twenty-six studies, seventeen focused on three or fewer cases (i.e., individuals), and fourteen of those seventeen studies were limited to single-patient studies.[154] The remainder of the studies assessed the association between acetaminophen and the relevant skin conditions, and the results were inconclusive.

119. Based on this suggestive but not overwhelming evidence, FDA stated in the communication that it would "also request that manufacturers add a warning about serious skin reactions to the product labels of OTC acetaminophen drug products marketed under a new drug application and will encourage manufacturers of drug products marketed under the OTC monograph do the same."[155]

120. In 2017, the FDA issued informal guidance that marketers of acetaminophen may include a rash warning without the risk of being prosecuted for misbranding.[156]

121. Even before that guidance was issued, JJCI voluntarily changed the Tylenol warning label to include a skin rash warning in or around 2015.

122. As the FDA recognized, marketers have a duty to warn the public about a drug's potential dangers, even if the underlying science is not conclusive. That makes eminent sense. Consumers ingesting a drug designed to treat minor aches, pains, and fever have a right to make an informed choice about possible risks they are willing to bear, even if those risks have not been established with scientific certainty.

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[153] *Id.*
[154] *Id.*
[155] *Id.*
[156] U.S. Food & Drug Admin, *Recommended Warning for Over-the-Counter Acetaminophen-Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions: Guidance for Industry* (Jan. 2017), https://www.fda.gov/media/90572/download.

123. Other examples abound. In 2014, for instance, AbbVie Inc., the marketer of DEPAKOTE® ("Depakote") (also known as valproate), a prescription medication used to treat epilepsy, filed a Supplemental New Drug Application ("sNDA") to add a warning regarding the potential risk for autism spectrum disorder to the pregnancy section of the prescribing information. AbbVie Inc. filed its sNDA after the publication of an observational study in JAMA, the same publication in which some of the aforementioned acetaminophen studies have been published. The Depakote study was a population-based cohort study of all children born in Denmark from 1996 to 2006.[157] The study focused on 508 children that had been exposed to the drug in utero and found an autism hazard ratio of 2.9 (95% CI 1.7–4.9).[158] The study authors concluded that "[m]aternal use of valproate during pregnancy was associated with a significantly increased risk of autism spectrum disorder and childhood autism in the offspring, even after adjusting for maternal epilepsy."[159]

124. In August 2014, the FDA approved AbbVie's sNDA and Section 8.1, pregnancy, of the prescribing information was amended to state:

> An observational study has suggested that exposure to valproate products during pregnancy may increase the risk of autism spectrum disorders. In this study, children born to mothers who had used valproate products during pregnancy had 2.9 times the risk (95% confidence interval [CI]: 1.7-4.9) of developing autism spectrum disorders compared to children born to mothers not exposed to valproate products during pregnancy. The absolute risks for autism spectrum disorders were 4.4% (95% CI: 2.6%-7.5%) in valproate-exposed children and 1.5% (95% CI: 1.5%-1.6%) in children not exposed to valproate products. Because the study was observational in nature, conclusions regarding a causal association between in utero valproate exposure and an increased risk of autism spectrum disorder cannot be considered definitive.[160]

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[157] Jakob Christensen et al., *Prenatal Valproate Exposure and Risk of Autism Spectrum Disorders and Childhood Autism*, 309 J. Am. Med. Ass'n 1696 (2013).
[158] *Id*. at 1696.
[159] *Id.*
[160] *Depakote ER Full Prescribing Information*, U.S. Food & Drug Admin. 28–29 (Aug. 2014), https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/021168s029lbl.pdf.

125. In or around 2019 or 2020, AbbVie submitted another sNDA to provide for a warning about the risk of in-utero ingestion of Depakote and the offspring developing ADHD. AbbVie's sNDA was prompted by another observational study published in JAMA that assessed prenatal exposure to valproate and the risk of ADHD.[161] That study was a population-based cohort study of all children born in Denmark from 1997 through 2011, and its results showed a hazard ratio of 1.48 (95% CI 1.09–2.00) that children exposed to valproate in-utero would develop ADHD.[162]

126. Following the FDA's approval of that additional warning for ADHD, the Depakote label included the following language to warn pregnant women of the possible risks of in-utero consumption:

> Although the available studies have methodological limitations, the weight of the evidence supports a causal association between valproate exposure in utero and subsequent adverse effects on neurodevelopment, including increases in autism spectrum disorders and attention deficit/hyperactivity disorder (ADHD). An observational study has suggested that exposure to valproate products during pregnancy increases the risk of autism spectrum disorders. In this study, children born to mothers who had used valproate products during pregnancy had 2.9 times the risk (95% confidence interval [CI]: 1.7-4.9) of developing autism spectrum disorders compared to children born to mothers not exposed to valproate products during pregnancy. The absolute risks for autism spectrum disorders were 4.4% (95% CI: 2.6%-7.5%) in valproate exposed children and 1.5% (95% CI: 1.5%-1.6%) in children not exposed to valproate products. Another observational study found that children who were exposed to valproate in utero had an increased risk of ADHD (adjusted HR 1.48; 95% CI, 1.09-2.00) compared with the unexposed children. Because these studies were observational in nature, conclusions regarding a causal association between in utero valproate exposure and an increased risk of autism spectrum disorder and ADHD cannot be considered definitive.[163]

[161] *See* Christensen et al., *supra* note 157.
[162] *Depakote ER Full Prescribing Information*, *supra* note 159.
[163] *Depakote ER Full Prescribing Information*, *supra* note 150.

127. There are still more examples. Take Singulair, a drug used to treat asthma, the label for which includes a black box warning—the strictest and most serious type of warning the FDA can require—that states:

> 5.1 Neuropsychiatric Events Serious neuropsychiatric (NP) events have been reported with use of SINGULAIR. These postmarketing reports have been highly variable and included, but were not limited to, agitation, aggressive behavior or hostility, anxiousness, depression, disorientation, disturbance in attention, dream abnormalities, dysphemia (stuttering), hallucinations, insomnia, irritability, memory impairment, obsessive-compulsive symptoms, restlessness, somnambulism, suicidal thoughts and behavior (including suicide), tic, and tremor. NP events have been reported in adult, adolescent, and pediatric patients with and without a previous history of psychiatric disorder. NP events have been reported mostly during SINGULAIR treatment, but some were reported after SINGULAIR discontinuation. Animal studies showed that montelukast distributes into the brain in rats [see Clinical Pharmacology (12.3)]; *however, the mechanisms underlying SINGULAIR-associated NP events are currently not well understood. Based upon the available data, it is difficult to identify risk factors for or quantify the risk of NP events with SINGULAIR use*.[164]

128. In 2022, a cohort study noted the fact that the underlying science for this black box warning was inconclusive: "The evidence base for adverse neuropsychiatric outcomes associated with LTMAs is *mixed and inconclusive*. Nevertheless, in 2020, the [FDA] issued a new warning about potential serious mental health outcomes associated with montelukast to promote further awareness of potential adverse effects and also advised reducing montelukast's use in the treatment of allergic rhinitis."[165]

129. By contrast, the body of scientific evidence showing a causal relationship between ASD/ADHD and prenatal ingestion of acetaminophen is overwhelming, consisting of at least 26 observational studies with over 170,000 people, and further corroborating animal studies. Given

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[164] *Singulair Full Prescribing Information*, U.S. Food & Drug Admin. 5 (April 2020), https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/020829s073,020830s075,021409s051lbl.pdf.

[165] Tapio Paljarvi et al., *Analysis of Neuropsychiatric Diagnoses After Montelukast Initiation*, JAMA Network Open 2 (May 24, 2022).

this compelling scientific evidence, it is incumbent on manufacturers of the acetaminophen products to use their labels to warn pregnant women that the drug can cause ASD and ADHD. Or at a minimum, they should warn pregnant women that many studies have found such an association. Yet JJCI has taken *no* steps to warn pregnant women of the dangers associated with prenatal ingestion of Tylenol. Instead, JJCI has continued marketing Tylenol as completely safe for pregnant women.

G. J&J Willfully Chose to Ignore the Risks of ASD Caused by Prenatal Use of Tylenol While Directing Its Other Subsidiary to Study ASD Causes and Profit from that Research.

130. The first sentence of J&J's credo states: "We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services."[166]

131. J&J's actions, however, suggest that it prioritizes profits for shareholders over the interests of all other stakeholders.

132. Based on information and belief, while JJCI, a J&J subsidiary, has concealed the risks of acetaminophen from pregnant women, J&J has directed another subsidiary, Janssen Research & Development, LLC ("Janssen"), to track ASD behaviors and other events.

133. Janssen operates the Janssen Autism Knowledge Engine, also known as JAKE® ("JAKE"), which is a "system of tools and technologies to optimize clinical trials for [ ] ASD."[167] The JAKE system was developed to facilitate the testing of medications that may treat the symptoms of ASD.

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[166] *Our Credo*, Johnson & Johnson, https://www.jnj.com/credo/ (last visited Dec. 13, 2022).
[167] Gahan Pandina, *47.4 Development of a System of Tools and Technologies to Optimize Clinical Trials for Autism Spectrum Disorders*, 55 J. Am. Acad. Child & Adolescent Psychiatry S334 (2016).

134. According to a publication written by Janssen researchers, "JAKE is a dynamically updated clinical research system developed to provide quantifiable and reproducible measures for use in assessing treatment outcomes, potentially including detection of change in ASD symptoms and ASD subgroup identification. JAKE is a three-part investigational system consisting of: My JAKE (a web and mobile application for use by caregivers and clinicians to log symptoms, record treatments, track progress, and gather comprehensive medical information); JAKE Sense (research biosensors and tasks designed to detect and monitor changes in experimental, proof-of-concept ASD biomarkers); and JAKE Stream (a system designed to collect, time-synchronize, and process data from both My JAKE [My JAKE Data Pipeline] and JAKE Sense [JAKE Sense Data Pipeline])."[168]

135. Through the My JAKE web-and-mobile application, a user can "log symptoms, demarcate events of interest, record treatments and medical information, and track overall study progress" for someone with ASD.[169] This data is collected and stored in the "Janssen Research Data Warehouse," where Janssen can analyze that data along with data collected from JAKE Sense biosensors.[170]

[168] Seth L. Ness et al., *An Observational Study with the Janssen Autism Knowledge Engine (JAKE®) in Individuals with Autism Spectrum Disorder*, 13 Frontiers in Neuroscience 4 (2019).
[169] *Id*. at 5.
[170] Seth L. Ness et al., *JAKE® Multimodal Data Capture System: Insights from an Observational Study of Autism Spectrum Disorder*, 11 Frontiers Neurosci. 2 (2017).

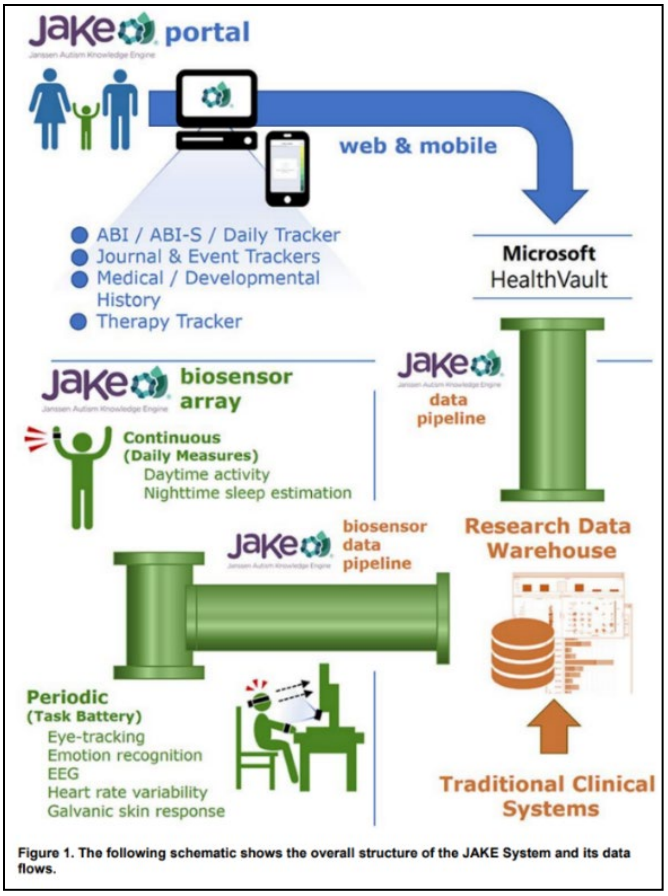

Figure 1. The following schematic shows the overall structure of the JAKE System and its data flows.

136. Based on information and belief, for many years, dating back to at least 2015 and continuing through the present date, Janssen, at the direction of J&J, has been tracking ASD patients throughout the United States and perhaps globally via My JAKE. Janssen collects the following data via My JAKE:

- ABI (Autism Behavior Inventory):[171] The ABI is based on 65 questions answered by the My JAKE user (typically, the caregiver for the person with ASD) related to the core and associated symptoms of ASD.[172]

[171] The ABI scale measures changes in core and associated symptoms in both children and adults with ASD. *See* Abi Bangerter et al., *Autism Behavior Inventory: A Novel Tool for Assessing Core and Associated Symptoms of Autism Spectrum Disorder*, 27 J. Childhood Adolescent Psychopharmacology 814 (2017). ABI includes allows measurement of social communication, restrictive repetitive behaviors, mental health, self-regulation, and challenging behavior. *Id*. at 819–20.

[172] Sarah Bonneux, *Janssen Autism Knowledge Engine (Jake®) System In Autism Spectrum Disorder*, Clinical Data Interchange Standards Consortium 2020 Europe Interchange Presentations

- ABI-S: A shorter version of the ABI.[173]

- Daily Tracker: Reports on the quality of sleep the previous night for the person with ASD and the user's observation of three ASD behaviors tracked on a daily basis.[174]

- Mood Report: Reports on the user's observation of the mood of the person with ASD in terms of "emotional valence and energy levels."[175]

- Journal and Event Trackers: Shows a log of events with descriptions that are meant to be recorded contemporaneously by the user. The user may enter this data in a journal style or choose from a list of common ASD events.[176]

- Therapy Tracker: Shows a log of care-related appointments, such behavioral, occupational, and speech therapy appointments, of the person with ASD, which can be displayed in weekly or monthly views.[177]

- Medical/Developmental History: Shows a detailed medical history and developmental history of the person of ASD.[178]

These data are reflected in the My JAKE user interface, as shown below:[179]

3–4, https://www.cdisc.org/sites/default/files/2021-02/2020_eu_interchange_paper_sbonneux_28feb.pdf.

[173] *Id.*

[174] *Id*.

[175] *Id* at 4.

[176] *Id*.

[177] *Id*.

[178] *Id*.

[179] Ness et al., *supra* note 168, at 7.

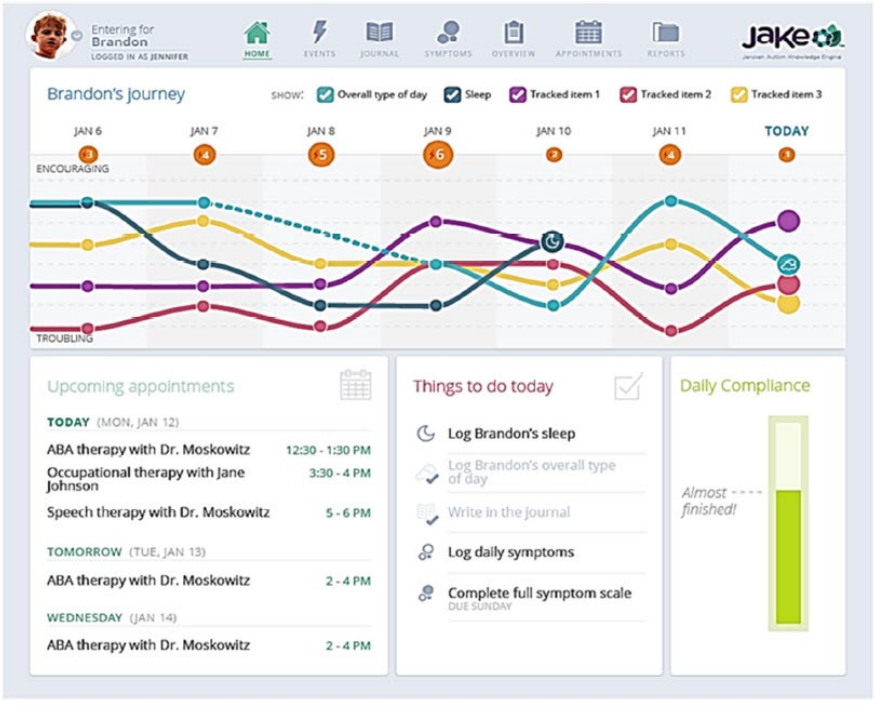

FIGURE 2 | Sample My JAKE home page. ABA, Applied behavior analysis.

137. In addition, Janssen tracks data from a mother's pregnancy:

138. Although Janssen tracks pregnancy data through its My JAKE application, at the direction of J&J, Janssen does not track whether mothers of children with ASD took Tylenol—or other acetaminophen products—while pregnant. Based on information and belief, J&J directs

Janssen to not track this information and purposefully fails to include prenatal use of acetaminophen as a data factor for JAKE. Meanwhile, JAKE contains a "therapy tracker" module, which allows for the "tracking of participants' medical treatments or therapies, using a calendar-like interface."[180]

139. For Janssen to collect health-related data concerning children with ASD, Janssen created the "My JAKE Data Pipeline," through which health records stored in a caregiver's or participant's Microsoft HealthVault account would be uploaded. After capturing these health records, data is directed to an internal Janssen server for traceability archiving/auditing and then ultimately to the Janssen data management team.

140. The My JAKE application has been touted as a tool to "test[] pharmaceutical compounds [in the near future] for the treatment of [ASD]."[181] J&J seeks to use JAKE to profit off the very ASD epidemic J&J, through JJCI, helped create by marketing pharmaceutical treatments while willfully continuing to turn a blind eye to the fact that its signature product, Tylenol, can cause ASD in children when taken by pregnant mothers.

141. On information and belief, following the publication of numerous scientific journal articles concerning the association between prenatal use of Tylenol and ASD, J&J and JJCI set out on a course to obscure the published science.

142. On information and belief, given that J&J and JJCI apparently chose to protect its brand rather than turning to the participating parents, caregivers, and health professionals to assess whether children with ASD who are monitored within the JAKE "Data Pipeline" were exposed to

[180] *Id.* at 6.

[181] Nanette Varian, *Meet the Man Who's Helping to Advance Autism Research*, https://www.jnj.com/innovation/janssen-autism-spectrum-disorder-research (last visited Dec. 13, 2022).

Tylenol while in utero, JJCI and J&J could only have been left with the ability to study a limited collection of post-marketing adverse events reported ("AERs") concerning acetaminophen. However, it is believed that within all AERs relative to acetaminophen, only a handful of AERs involved children with claimed ASD.

143. On further information and belief, the efforts to rebuke and downplay the science that shows prenatal use of Tylenol can cause ASD and/or ADHD has been a collective effort by J&J, Janssen, and JJCI.

H. Plaintiff Mothers Took Acetaminophen While Pregnant, Causing Plaintiff Children to Develop ASD and/or ADHD.

144. JJCI's concerted efforts to represent Tylenol as safe for prenatal ingestion has worked all too well, and mothers have relied on its representations and took Tylenol while pregnant.

145. The mothers of Plaintiff Children ingested Tylenol that was designed, manufactured, tested, marketed, labeled, packaged, handled, distributed, stored, and/or sold by JJCI while the mothers were pregnant with Plaintiff Children.

146. As a result of their mothers' prenatal use of Tylenol, Plaintiff Children developed ASD and ADHD.

147. At all relevant times, JJCI knew or should have known that there was a significant risk of ASD and/or ADHD in children when Plaintiff Children were exposed in utero to Tylenol.

148. Despite this, JJCI failed to include *any* warning regarding the risks of a child developing ASD and/or ADHD when exposed to Tylenol in utero or to otherwise communicate these risks to pregnant women.

149. JJCI thus failed to adequately warn Plaintiff mothers about the increased risk of developing ASD and/or ADHD if a pregnant woman ingested Tylenol.

150. Had Plaintiff mothers known the risks associated with prenatal use of Tylenol, and that it could cause ASD and/or ADHD in children, Plaintiff mothers would not have ingested Tylenol while pregnant with Plaintiff Children or would have dramatically limited their consumption to brief periods of use.

151. As a direct and proximate cause of JJCI's conduct, Plaintiff Children as well as Plaintiff Parents suffered serious and/or permanent injuries, and/or adverse effects as set forth in the individual Short Form Complaints or any other responsive discovery adduced in the respective constituent actions.

152. As a direct and proximate result of the acts and omissions of JJCI, and Plaintiff mothers' use of Tylenol and the resulting injuries, Plaintiffs have suffered damages and harm, including but not limited to, emotional distress. Plaintiffs have incurred other medical expenses and other economic harm, as well as loss of consortium, services, society, companionship, love and comfort.

153. As a direct and proximate result of the acts and omissions of JJCI, and Plaintiffs' use of Tylenol, Plaintiffs have been prevented from pursuing their normal activities and employment, have experienced severe pain and suffering and mental anguish, and have been deprived of their ordinary pursuits and enjoyments of life, and have and/or will suffer diminution of earnings as a result.

154. To the extent that the law of another forum is applied to any aspect of the case, Plaintiffs incorporate by reference that law and make any and all claims that may be available under the law.

TOLLING/FRAUDULENT CONCEALMENT

155. Plaintiffs assert all applicable statutory and common law rights and theories related to the tolling or extension of any applicable statutes of limitations, including minor tolling, equitable tolling, delayed discovery, discovery rule and/or fraudulent concealment.

156. The discovery rule applies to toll the running of the statute of limitations until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of their injuries, the cause of their injuries, and the tortious nature of the wrongdoing that caused their injuries.

157. The nature of Plaintiffs' injuries, damages, or their causal relationship to JJCI's conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiffs' claims.

158. The running of the limitations period is also equitably tolled. JJCI is estopped from relying on any statutes of limitation or repose by virtue of its fraudulent concealment, through affirmative misrepresentations, *see, e.g.*, *supra* ¶¶ 110–11 & 113, and omissions to Plaintiff Children and Plaintiff mothers regarding the safety of Tylenol. Based on information and belief, JJCI affirmatively withheld and/or misrepresented facts concerning Tylenol's safety. As a result of JJCI's misrepresentations and concealment, Plaintiffs' mothers were unaware, and could not have known or have learned through reasonable diligence, of facts related to their exposed to the risks alleged herein or that those risks were the direct and proximate result of the wrongful acts and/or omissions of JJCI.

159. JJCI's affirmative actions of concealment by failing to disclose this known but non-public information about the defects—information over which JJCI had exclusive control—and because Plaintiffs could not reasonably have known that Tylenol could cause ASD and/or ADHD

when exposed in utero, JJCI is estopped from relying on any statutes of limitations or repose that might otherwise be applicable to the claims asserted herein.

EXEMPLARY PUNITIVE DAMAGES ALLEGATIONS

160. JJCI's conduct as alleged herein was done with reckless disregard for human life, oppression, and malice. JJCI was fully aware of Tylenol's safety risks, including that injuries from Tylenol's inadequate label could cause ASD or ADHD in children when exposed in utero. Nonetheless, JJCI deliberately crafted its label and marketing to mislead consumers and profit from the lucrative sales to pregnant women.

161. This was not done by accident or through some justifiable negligence. Rather, JJCI knew it could profit by convincing consumers that Tylenol was *the* safe form of pain reliever for pregnant women. Plaintiff mothers were denied the right to make an informed decision about whether to use Tylenol while pregnant. JJCI's conduct was done with conscious disregard of Plaintiffs' rights.

162. In addition, and as stated, *supra* ¶¶ 130–143, JJCI is affirmatively concealing the risks associated with prenatal ingestion of acetaminophen while its parent is seeking to profit off of the very injuries that result from prenatal ingestion of acetaminophen. J&J has created the JAKE database and engaged in conduct related thereto that rather than addressing Tylenol's safety concerns through warnings or other actions, instead focuses on seeking to profit from the development of therapies to treat Plaintiffs' and others' neurodevelopmental disorders.

163. JJCI's aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, malicious, and deliberate disregard for the rights and safety of consumers, including Plaintiffs, thereby entitling Plaintiffs to punitive damages in an amount

appropriate to punish JJCI and deter it from similar conduct in the future. Plaintiffs may also require additional medical and/or hospital care, attention, and services in the future.

164. Accordingly, Plaintiffs request punitive damages (where available) against JJCI for the harms caused to Plaintiffs.

CAUSES OF ACTION

COUNT I: STRICT LIABILITY FOR FAILURE TO WARN

165. Plaintiffs incorporate by reference paragraphs 1–164 as if each were set forth fully and completely herein.

166. At all relevant times, Tylenol was under the exclusive control of JJCI. JJCI designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and/or sold Tylenol, including the Tylenol ingested by Plaintiff mothers while pregnant with Plaintiff Children.

167. JJCI had an ongoing duty to warn Plaintiffs of the risks and latent dangers associated with the use of Tylenol.

168. JJCI, as a manufacturer of drugs, is held to the level of knowledge of an expert in the field and, further, JJCI had knowledge of the dangerous risks and side effects of Tylenol.

169. Acetaminophen, the sole active ingredient in Tylenol, can cause ASD and/or ADHD in children. JJCI knew or should have known about these risks and had a duty to warn Plaintiffs about them.

170. Nonetheless, although the Tylenol labels warn of various risks (including at least one warning that is not required by federal law), JJCI has never warned pregnant women that ingestion of acetaminophen while pregnant can cause ASD and/or ADHD.

171. The only warning relating to pregnancy on Tylenol labels during the relevant time period stated, "if pregnant or breast-feeding, ask a health professional before use."

172. That warning is used in "all over-the-counter (OTC) drug products that are intended for systemic absorption," 21 C.F.R. § 201.63, and does not adequately warn pregnant women of the specific risks that prenatal ingestion of Tylenol may cause children to develop ASD and/or ADHD.

173. The warnings that accompanied Tylenol failed to provide the level of information that an ordinary consumer would expect when using the product in a manner reasonably foreseeable to JJCI.

174. JJCI knew or should have known that prenatal ingestion of acetaminophen could cause ASD and/or ADHD in children and that the minimal warnings disseminated with Tylenol were inadequate, failed to communicate adequate information on the dangers and risks of Tylenol, and failed to communicate warnings and instructions that were appropriate and adequate to render Tylenol safe for its ordinary, intended and reasonably foreseeable uses.

175. JJCI's promotional activities further diluted or minimized the warnings given with Tylenol by misrepresenting the safety, risks, and benefits of Tylenol in order to advance its own financial interests.

176. Specifically, JJCI has marketed Tylenol as a pain reliever that is safe for pregnant women to use.

177. JJCI therefore breached its duty to warn consumers of the risks associated with prenatal ingestion of Tylenol.

178. Plaintiff mothers were foreseeable users of Tylenol.

179. At all relevant times, Plaintiff mothers used Tylenol in the manner in which the drug was intended to be used.

180. Tylenol, when it was ingested by Plaintiff mothers, was in the same condition as when it was designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold by JJCI.

181. Plaintiff mothers ingested Tylenol while pregnant with Plaintiff Child, and the Plaintiff Child's in utero exposure to Tylenol caused Plaintiff Child to develop ASD and/or ADHD.

182. Plaintiff mothers did not know and could not have reasonably been expected to know of the risks associated with prenatal ingestion of acetaminophen.

183. At the time Plaintiff mothers used Tylenol, the drug was unreasonably dangerous to Plaintiff Children because of Tylenol's inadequate warning.

184. Had Plaintiff mothers received proper or adequate warnings and/or instructions of the risks of using Tylenol while pregnant, they would have read and heeded those warnings and/or instructions and could have obtained or used alternative medication. As a result, Plaintiff mothers would not have ingested Tylenol while pregnant and Plaintiff Children would not have been injured.

185. JJCI's lack of adequate warnings and instructions accompanying Tylenol was a substantial factor in causing Plaintiffs' injuries.

186. As a direct and proximate result of JJCI's failure to provide adequate warnings of the risks of Tylenol, Plaintiffs have been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other

damages. Plaintiff Children may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT II: STRICT LIABILITY FOR DESIGN DEFECT DUE TO INADEQUATE WARNINGS AND PRECAUTIONS

187. Plaintiffs incorporate by reference paragraphs 1–186 as if each were set forth fully and completely herein.

188. At all relevant times, Tylenol was under the exclusive control of JJCI. JJCI designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and/or sold Tylenol, including the Tylenol ingested by Plaintiff mothers while pregnant with Plaintiff Children.

189. JJCI had an ongoing duty to design Tylenol with adequate warnings to alert Plaintiffs of the risks and latent dangers associated with the use of Tylenol.

190. JJCI, as a manufacturer of drugs, is held to the level of knowledge of an expert in the field and, further, JJCI had knowledge of the dangerous risks and side effects of Tylenol.

191. Acetaminophen, the sole active ingredient in Tylenol, can cause ASD and/or ADHD in children. JJCI knew or should have known about these risks and had a duty to design Tylenol with adequate warnings.

192. Nonetheless, although the Tylenol labels warn of various risks (including at least one warning that is not required by federal law), JJCI has never warned pregnant women that ingestion of acetaminophen while pregnant can cause ASD and/or ADHD.

193. The only warning relating to pregnancy on Tylenol labels during the relevant time period stated, "if pregnant or breast-feeding, ask a health professional before use."

194. That warning is used in "all over-the-counter (OTC) drug products that are intended for systemic absorption," 21 C.F.R. § 201.63, and does not adequately warn pregnant women of the specific risks that prenatal ingestion of Tylenol may cause children to develop ASD and/or ADHD.

195. The warnings that accompanied Tylenol failed to provide the level of information that an ordinary consumer would expect when using the product in a manner reasonably foreseeable to JJCI.

196. JJCI knew or should have known that prenatal ingestion of acetaminophen could cause ASD and/or ADHD in children and that the minimal warnings disseminated with Tylenol were inadequate, failed to communicate adequate information on the dangers and risks of Tylenol, and failed to communicate warnings and instructions that were appropriate and adequate to render Tylenol safe for its ordinary, intended and reasonably foreseeable uses.

197. JJCI's promotional activities further diluted or minimized the warnings given with Tylenol by misrepresenting the safety, risks, and benefits of Tylenol in order to advance its own financial interests.

198. Specifically, JJCI has marketed Tylenol as a pain reliever that is safe for pregnant women to use.

199. JJCI therefore breached its duty to design Tylenol with adequate warnings of the risks associated with prenatal ingestion of Tylenol.

200. At all relevant times, Tylenol was defective as marketed because it posed a risk of injury to consumers who used Tylenol in a reasonably foreseeable manner, since Tylenol was

marketed without adequate warnings of the risks of ASD and/or ADHD in the children of women who ingested Tylenol while pregnant. At all relevant times, Tylenol was defective at the time it left JJCI's control. No extrinsic changes were made to alter the Tylenol products that JJCI manufactured.

201. Plaintiff mothers were foreseeable users of Tylenol.

202. At all relevant times, Plaintiff mothers used Tylenol in the manner in which the drug was intended to be used.

203. Tylenol, when it was ingested by Plaintiff mothers, was in the same condition as when it was designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold by JJCI.

204. Plaintiff mothers ingested Tylenol while pregnant with Plaintiff Child, and the Plaintiff Child's in utero exposure to Tylenol caused Plaintiff Child to develop ASD and/or ADHD.

205. Plaintiff mothers did not know and could not have reasonably been expected to know of the risks associated with prenatal ingestion of acetaminophen.

206. At the time Plaintiff mothers used Tylenol, the drug was unreasonably dangerous to Plaintiff Children because of Tylenol's inadequate warning.

207. Had Plaintiff mothers received proper or adequate warnings and/or instructions of the risks of using Tylenol while pregnant, they would have read and heeded those warnings and/or instructions and could have obtained or used alternative medication. As a result, Plaintiff mothers would not have ingested Tylenol while pregnant and Plaintiff Children would not have been injured.

208. JJCI's lack of adequate warnings and instructions accompanying Tylenol was a substantial factor in causing Plaintiffs' injuries.

209. As a direct and proximate result of JJCI's failure to provide adequate warnings of the risks of Tylenol, Plaintiffs have been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff Children may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT III: NEGLIGENCE

210. Plaintiffs incorporate by reference paragraphs 1–209 as if each were set forth fully and completely herein.

211. At all relevant times, Tylenol was under the exclusive control of JJCI, and JJCI designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and/or sold Tylenol.

212. At all relevant times, JJCI had a duty to design, label, package, manufacture, test, distribute, and sell Tylenol with reasonable and due care for the safety and well-being of Plaintiffs, who were subject to and used the product.

213. Acetaminophen or APAP, the sole active ingredient in Tylenol, can cause ASD and/or ADHD in offspring when a woman ingests the drug while pregnant. JJCI knew or should

have known about each of these risks and warned consumers about same, specifically warning pregnant women.

214. Tylenol labels warn of various risks, including at least one warning that is not required by federal law, but nothing on the Tylenol label warns pregnant women that ingestion of acetaminophen while pregnant can cause ASD and/or ADHD. The warnings that accompanied Tylenol thus failed to provide the level of information that an ordinary consumer would expect when using the product in a manner reasonably foreseeable to JJCI.

215. JJCI therefore breached its duty to consumers, including Plaintiffs, to communicate the risks associated with prenatal ingestion of acetaminophen with reasonable care.

216. Plaintiff mothers were foreseeable users of Tylenol.

217. At all relevant times, Plaintiff mothers used Tylenol in the manner in which the drug was intended to be used.

218. Tylenol, when it was ingested by Plaintiff mothers, was in the same condition as when it was designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold by JJCI.

219. Plaintiff mothers did not know and could not have reasonably been expected to know of the risks associated with prenatal ingestion of acetaminophen.

220. Plaintiff mothers ingested Tylenol while pregnant with Plaintiff Child, and the Plaintiff Child's in utero exposure to Tylenol caused Plaintiff Child to develop ASD and/or ADHD.

221. Plaintiffs' injuries were reasonably foreseeable to JJCI because it knew or should have known that prenatal ingestion of acetaminophen could cause ASD and/or ADHD in children and that the minimal warnings disseminated with Tylenol failed to communicate warnings and

instructions that were appropriate and adequate to render Tylenol safe for its ordinary, intended and reasonably foreseeable uses.

222. Had JJCI used reasonable care in communicating adequate warnings and/or instructions of the risks of using Tylenol while pregnant, Plaintiff mothers would have read and heeded those warnings and/or instructions and could have obtained or used alternative medication. As a result, Plaintiff mothers would not have ingested Tylenol while pregnant and Plaintiff Children would not have been injured.

223. JJCI's lack of adequate warnings and instructions accompanying Tylenol was a substantial factor in causing Plaintiffs' injuries.

224. As a direct and proximate result of JJCI's failure to provide adequate warnings of the risks of Tylenol, Plaintiffs have been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff Children may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiffs respectfully request this Court enter judgment in Plaintiffs' favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IV: NEGLIGENT MISREPRESENTATION BY OMISSION
(Alabama, Alaska, Arizona, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nevada, New Jersey, New Mexico, New York, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Utah, Vermont, Virginia, Washington, Washington DC, West Virginia, and Wisconsin)

225. Plaintiffs incorporate by reference paragraphs 1–224 as if each were set forth fully and completely herein.

226. At all relevant times, JJCI designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, sold and/or otherwise released into the stream of commerce Tylenol and exercised control over Tylenol.

227. At the time the Tylenol left JJCI's possession, it was in the same condition as when it was ingested by Plaintiff mothers.

228. JJCI, as the manufacturer and distributor of Tylenol, owed a duty to the consuming public in general and Plaintiffs in particular, to provide accurate, truthful, and complete information about the risks and benefits of using Tylenol when used in the intended manner and for the intended purpose.

229. Acetaminophen or APAP, the sole active ingredient in Tylenol, can cause ASD and/or ADHD in children when a woman ingests the drug while pregnant.

230. JJCI knew or should have known about each of these risks to warn consumers, specifically pregnant women.

231. The Tylenol label mispresents its safety because the label omits the risk of a child developing ASD and/or ADHD from in utero exposure to acetaminophen.

232. JJCI breached its duty of care to Plaintiffs in the labeling, packaging, distribution, marketing, and/or sale of Tylenol.

233. JJCI knew or should have known its statements regarding the safety of Tylenol constituted misrepresentations for failing to disclose the risk of a child developing ASD and/or ADHD from in utero exposure to acetaminophen.

234. JJCI intended for Plaintiffs and Plaintiff mothers to rely on these misrepresentations

235. These consumers and Plaintiffs were foreseeable recipients of JJCI's misrepresentations

236. JJCI knew that pregnant women, like Plaintiff mothers, would rely on its misrepresentations regarding the safety of Tylenol, which omitted the risk of a child developing ASD and/or ADHD from in utero exposure to acetaminophen .

237. Because of JJCI's representations to Plaintiff mothers regarding the safety of Tylenol failed to disclose the risk of a child developing ASD and/or ADHD from in utero exposure to acetaminophen, Plaintiff mothers relied on JJCI's misrepresentations and ingested Tylenol while pregnant with Plaintiff Children.

238. As a result of Plaintiff mothers' reliance, Plaintiff Children were injured in that they developed ASD and/or ADHD due to their in-utero exposure to Tylenol.

239. It was foreseeable that JJCI's misrepresentations, actions, and omissions would cause severe, permanent, and debilitating injuries to Plaintiffs.

240. JJCI's conduct was a substantial factor in causing Plaintiffs' injuries.

241. As a direct and proximate result of JJCI's negligence, Plaintiffs have been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiffs may also require additional medical and/or hospital care, attention, and services in the future.

COUNT V: BREACH OF IMPLIED WARRANTY

242. Plaintiffs incorporate by reference paragraphs 1–241 as if each were set forth fully and completely herein.

243. At all relevant times, Tylenol was under the exclusive control of JJCI. JJCI designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and/or sold

Tylenol, including the Tylenol ingested by Plaintiff mothers while pregnant with Plaintiff Children.

244. At all relevant times, JJCI intended that pregnant women purchase and ingest Tylenol, and JJCI impliedly warranted Tylenol to be of merchantable quality and fit for such use.

245. Plaintiff mothers were foreseeable users of Tylenol.

246. JJCI knew or had reason to know that Plaintiff mothers would rely on JJCI's judgment and representations regarding the safety of Tylenol for pregnant women.

247. Tylenol was expected to reach and did reach consumers, including Plaintiff mothers, without substantial change in the condition in which it was manufactured and sold by JJCI.

248. JJCI breached various implied warranties with respect to Tylenol in that it was not fit for its intended purpose or ordinary use, and specifically, that JJCI represented that Tylenol was safe for pregnant women and would not cause ASD and/or ADHD in children when exposed in utero.

249. In reliance upon JJCI's implied warranty, Plaintiff mothers ingested Tylenol while pregnant with Plaintiff Children in the foreseeable manner normally intended, recommended, promoted, and marketed by JJCI.

250. JJCI's breach of its implied warranty regarding Tylenol was a substantial factor in causing Plaintiffs' injuries.

251. As a direct and proximate result of JJCI's breach of implied warranty regarding Tylenol, Plaintiffs have been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages.

Plaintiff Children may also require additional medical and/or hospital care, attention, and services in the future.

JURY TRIAL DEMAND

252. Pursuant to Federal Rule of Civil Procedure 38(b) Plaintiffs hereby demand a trial by jury on all the triable issues within this pleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the Court to enter judgment in Plaintiffs' favor and against JJCI for:

a. actual or compensatory damages in such amount to be determined at trial and as provided by applicable law;

b. exemplary and punitive damages sufficient to punish and deter JJCI and others from future wrongful practices;

c. pre-judgment and post-judgment interest;

d. reasonable attorneys' fees as provided by law;

e. costs and expenses of these actions;

f. statutory damages, treble damages and other relief permitted by the laws of the states that will govern these actions; and

g. any other relief the Court may deem just and proper.

Dated: July 25, 2023

Respectfully submitted,

/s/ Ashley C. Keller
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